

Application Number 10/730,878
Responsive to Office Action mailed February 20, 2007

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REMARKS

This Amendment is responsive to the Office Action dated February 20, 2007. Applicant has amended claims 3, 9, and 13, and added new claims 19 and 20. Claims 1-20 are pending.

Amendments to the Specification

With the present amendment, Applicant has amended paragraph [0002] to update the serial numbers for co-pending patent applications referenced in the originally filed disclosure. Applicant has also amended paragraph [0058] to briefly discuss the lead connection module embedded within an overmold, depicted in FIGS. 8A and 8B. By these amendments, Applicant provides additional support in the written description for the amendment to claims 3, 9, and 13. This amendment is fully supported by FIGS. 8A and 8B as originally filed and, therefore, adds no new matter.

Applicant has also amended paragraphs [0031] and [0032] to discuss hermetically sealed housings as described, for example, at paragraphs [0062]-[0064] in co-pending application serial number 10/731,869, which Applicant incorporated by reference. By these amendments, Applicant provides additional support in the written description for new claims 19 and 20. This amendment is fully supported by, for example, paragraphs [0062]-[0064] in co-pending application serial number 10/731,869, which was incorporated by reference in its entirety in Applicant's originally filed disclosure and, therefore, adds no new matter.

Claim Rejection Under 35 U.S.C. § 102(e)

In the Office Action, the Examiner rejected claims 1-13 and 15-18 under 35 U.S.C. § 102(e) as being anticipated by Berrang et al. (U.S. Patent No. 6,358,281, herein referred to as Berrang). Applicant respectfully traverses the rejection. Berrang fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Berrang fails to teach or suggest an implantable medical device comprising at least two interconnected modules, each of the modules comprising a respective one of at least two housings and an overmold that at least partially encapsulates each of the housings, the

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overmold comprising a lead connection module configured to accept an external lead, as recited by Applicant's independent claim 1.

Similarly, with respect to independent claim 9 as amended, Berrang fails to disclose or suggest an overmold for a modular implantable medical device that includes a plurality of modules, each of the modules comprising a respective housing, the overmold comprising a first material configured to hold at least part of the housing of one of the modules, a second material coupled to the first material, and a lead connection module configured to accept an external lead, the lead connection module being embedded within the overmold.

Additionally, Berrang fails to disclose or suggest an implantable medical device comprising at least two interconnected modules, each of the modules comprising a respective one of at least two housings and an overmold that partially encapsulates each of the housings and defines a frame configured to fix a position of the at least two interconnected modules relative to one another, the overmold comprising a lead connection module configured to accept an external lead, as recited by independent claim 16.

In support of the rejection of independent claims 1, 9, and 16, the Examiner characterized elements 2 and 3, shown in FIGS. 2 and 3, as two modules that each having a housing encapsulated by an overmold.¹ However, Berrang's disclosure clearly and repeatedly describes its device as having a single housing ("the housing") comprising two sections.² At no time does Berrang teach or even suggest that its device includes at least two interconnected modules that each comprise a respective housing, much less an overmold that at least partially encapsulates the housings, as recited by Applicant's independent claims 1 and 16 or an overmold comprising a first material configured to hold at least part of a housing of one of a plurality of modules and second material, as recited by Applicant's independent claim 9.

As taught by column 11, lines 60-63 of Berrang's disclosure, medical grade epoxy (or any biocompatible polymer) 28 is used to coat and encapsulate the internal components (mounted on the ceramic substrates 24 and 25) of elements 2 and 3. Berrang clearly teaches that the outside edges of the ceramic substrates 24 and 25, or the areas over the snap domes 20 and 23 are not coated by the epoxy.³ Thus, the epoxy surfaces are not housings for elements 2 and 3, as the

¹ Office Action at page 2, item 4.

² Berrang, columns 3-4, lines 25-4 and column 9, lines 51-62.

³ *Id.*

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Office Action suggests because the epoxy surfaces in no way house elements 2 and 3 as required by a housing. Rather, the epoxy surfaces are merely components of elements 2 and 3.

The Office Action found that column 12, lines 8-25 of Berrang teaches that an overmold encapsulates each of the " housings " of elements 2 and 3. Applicant respectfully disagrees, and submits that the Examiner has misinterpreted the scope and content of Berrang. At column 12, lines 8-25, Berrang teaches that the epoxy surfaces 28 and 31 are covered with a gold layer, which is designed to bond directly to the outside edge of the ceramic substrates 24 and 25, thus creating a sealed, hermetic covering over the components mounted onto each of the ceramic substrates 24 and 25. FIG. 2 illustrates a gold foil 27 surrounding the entire Berrang device. This layer of gold is not an overmold, as suggested by the Office Action. Instead, the gold layer forms a single housing for elements 2 and 3, and elements 2 and 3 are two sections within the single housing.⁴

As previously discussed, the elements 2 and 3 do not have separate housings. The elements 2 and 3 of Berrang share a housing (i.e., the gold layer), and in no way have respective housings, as required by Applicant's independent claims. Nothing in Berrang teaches or suggests that elements 2 and 3 are enclosed in a housing other than the gold layer so as to be considered modules each comprising a respective one of at least two housings. Furthermore, because the gold layer is the housing for elements 2 and 3, which the Office Action characterized as "modules," the gold layer cannot be an overmold that at least partially encapsulates each of the housings of the at least two interconnected modules, as required by claims 1 and 16. Similarly, the gold layer cannot hold at least part of a housing of a module, as required by claim 9, because the gold layer is the housing of the elements 2 and 3.

In an alternative interpretation, the Office Action characterized electronics 21 and battery 18 of Berrang as two modules, each with a respective housing at least partially encapsulated by an overmold.⁵ The Office Action further stated that electronics 21 are housed by support disc 33 and the epoxy and gold act as the overmold.⁶ However, Berrang's disclosure does not disclose or suggest that support disc 33 provides a housing for electronics 21.

⁴ See *id.* at column 9, lines 58-62 and column 3, lines 32-35.

⁵ Office Action at pages 2-3, item 4.

⁶ *Id.*

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Berrang describes piezoceramic actuators 19 and 22 that are each preferably mounted to a flexible support disc 32 and 33, respectively.⁷ Snap domes 20 and 23 may be pushed to cause piezoceramic actuators 19 and 22 on flexible support discs 32 and 33 to slightly bend thereby creating a voltage pulse sufficient to activate the electronics.⁸ Support disc 33 does not house electronics 21 and, rather, provides a mounting surface for piezoceramics actuator 22. Further, as illustrated in FIG. 2, support disc 33 is located proximate to one edge of electronics 21 but not the other surfaces of electronics 21. Support disc 33 does not in any way house electronics 21. Berrang fails to disclose or suggest at least two housings and, accordingly, fails to disclose or suggest the requirements of independent claims 1, 9, and 16.

For purposes of clarification, Applicant has amended claim 9 to recite a lead connection module within an overmold. Berrang does not disclose or suggest a lead connection module embedded within an overmold, as required by independent claim 9, or an overmold comprising a first material and a second material and a lead connection module that is embedded within the first material, as recited by Applicant's dependent claims 3 and 13. In support of the rejection of claims 3 and 13, Office Action found that a lead connection module is deployed with a first material of an overmold "because the lead conductors must pass through all coating materials . . . to reach the outside of the device."⁹ Applicant assumes the Office Action is referring to cables 7 and 8 in FIG. 2 as the "lead conductors."

Berrang does not teach or suggest an overmold, much less a lead connection module embedded within the overmold. Even if the coating materials are an overmold, as the Office Action suggests and Applicant disagrees with, lead conductors passing through coating materials do not amount to a lead connection module that is embedded in an overmold. Berrang describes neither a lead connection module nor a relationship between a lead connection module and an overmold, and thus, cannot anticipate Applicant's claims 3, 9 or 13.

The Office Action appears to be relying on an inherent disclosure in Berrang to support the rejection of claims 3, 9, and 13. The fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic.¹⁰ The

⁷ Berrang, column 12, lines 32-35.

⁸ *Id.* at 35-42.

⁹ Office Action at page 3, item 6.

¹⁰ *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ.2d 1955, 1957 (Fed. Cir. 1993); MPEP § 2112.

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Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.¹¹ Nothing in Berrang reasonably supports the assertion that its device includes a lead connection module, or that the lead connection module is embedded within an overmold. For example, Applicant submits that based on the teachings of Berrang¹², it is just as plausible for the cables 7 and 8 to be introduced through an opening in the coatings of Berrang to connect to housing sections 2 and 3, which the Office Action characterized as an overmold. In such a case, the cables 7 and 8 could not be properly characterized as a lead connection module, much less a lead connection module embedded within an overmold. As Applicant's disclosure teaches, a lead connection module is configured to accept an external lead.¹³ In the case of electronic leads, for example, a lead connection module may include one or more conductors that electrically couple an external lead to another module of the implantable medical device.¹⁴

Berrang also fails to disclose or suggest a lead connection module including a mechanical lead securing mechanism, as recited by claim 6. Furthermore, with respect to claim 7, Berrang fails to disclose or suggest a tool-less mechanical lead securing mechanism. In support of the rejection of claims 6 and 7, the Office Action stated that the lead connection module necessarily includes a mechanical lead securing mechanism because the lead is attached to the device, and the securing device is tool-less because it is integral. Applicant submits that the Examiner is relying on an improper inherent disclosure analysis. Berrang does not teach a lead connection module, and to the extent Berrang describes cables 7 and 8 connecting to the device, Berrang merely states that, "[t]he microphone casing 14 and electrode array 10 are connected to the housing sections 2 and 2 via junction 16 where cables 7 and 8 merge. Berrang does not describe a mechanical mechanism for securing cables 7 and 8 to the device.

Berrang describes a cable that is bonded to a substrate.¹⁵ The cable is preferably comprised of a bioinert film encapsulating lithographically formed wires. Openings in the film

¹¹ *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112.

¹² *E.g.*, Column 11, lines 1-3 and FIG. 2.

¹³ *See, e.g.*, paragraph [0035].

¹⁴ Applicant's disclosure at paragraph [0035].

¹⁵ Berrang at column 3, lines 42-50.

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allow electrical connections to be made between the wires and the substrate. The film is further bonded to an underlying gold foil substrate. Berrang fails to disclose or suggest a mechanical mechanism that secures the cable to the housing and, instead, describes bonds between materials that provide the connection. For the same reasons, Berrang also fails to disclose or suggest a tool-less mechanical lead securing mechanism. For at least these reasons, Berrang fails to disclose or suggest each and every element of claims 6 and 7.

Additionally, with respect to claim 15, Berrang fails to disclose or suggest that the housings are horizontally distributed at respective locations of the overmold, and separately encapsulated by the overmold. In support of the rejection of claim 15, the Office Action cited Berrang's FIG. 2. As described previously with respect to independent claims 1, 9, and 16, Berrang does not teach or suggest an overmold. However, even if the gold foil 27 is an overmold, which the Office Action proposes and Applicant disagrees with, the gold foil 27 surrounds an outer surface of the entire structure shown in Berrang's Figure 2 creating a common cavity in which both elements 2 and 3 reside. The gold foil does not separately encapsulate the elements 2 and 3, which the Office Action reasoned includes separate housings. For at least these reasons, Berrang fails to disclose or suggest the requirements of claim 15.

Berrang fails to disclose each and every limitation set forth in independent claims 1, 9, and 16. Claims 2-8, 10-13, 15, and 17-18 depend from one of independent claims 1, 9 or 16. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-13 and 15-18 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected claim 14 under 35 U.S.C. § 103(a) as being unpatentable over Berrang. Applicant respectfully traverses the rejection to the extent such rejections. As described above, Berrang fails to disclose or suggest the inventions defined by Applicant's claim 9, from which claim 14 depends, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention. Accordingly, Berrang fails to disclose or suggest the requirements of claim 9 for at least the reasons stated previously in this Amendment.

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For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claim 14 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

New Claims

Applicant has added claims 19 and 20 to the pending application. No new matter has been added by the new claims. None of the references of record disclose or suggest the inventions defined by Applicant's new claims, or provide any teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

For example, Berrang fails to disclose or suggest at least one hermetically sealed housing, as recited by new claims 19 and 20. The Office Action reasoned that column 11, line 55 of Berrang taught at least two interconnected modules each having a housing.¹⁶ As previously discussed, at column 11, line 55, Berrang teaches an epoxy that is used to coat and encapsulate the internal components of elements 2 and 3 (which the Office Action proposed are "modules"). Berrang specifically states that "[s]ince the epoxy, or other, encapsulation (over the ceramic substrate) does not provide a true hermetic or hermetic like seal," a gold coating is provided over the encapsulant surface.¹⁷ FIG. 2 of Berrang shows the gold coating as overlying the entire device. Thus, if the epoxy of Berrang is a "housing" as the Office Action proposes (and Applicant traverses), it is clear that Berrang does not teach or suggest at least one hermetically sealed housing, as recited by new claims 19 and 20.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references.

¹⁶ Office Action at page 2, item 4.

¹⁷ Berrang at column 3, lines 59-65.

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Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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